

What is claimed is:

1. An arterial cannula with associated filter, comprising:
 - a blood cannula having an outer surface, a distal end adapted to enter an artery, a proximal end adapted to receive blood or other fluids, and a lumen which extends longitudinally from the proximal to the distal end;
 - 5 an expandable filter disposed about the distal end of the blood cannula which is expandable between a contracted condition and an enlarged condition; and
 - 10 an occluder which is expandable between a contracted condition and an expanded condition, wherein the occluder, when in the contracted condition, is closely associated with the distal end of the blood cannula at a region proximal the mesh, while the occluder expands upon activation to substantially occlude an artery upstream of the mesh.
2. The arterial cannula of claim 1, wherein the proximal end 15 of the blood cannula is adapted to receive blood from a bypass-oxygenator machine.
3. The arterial cannula of claim 2, wherein the occluder is a balloon occluder comprising a flexible material surrounding a chamber.
4. The arterial cannula of claim 3, wherein the filter includes 20 an expansion frame which comprises an umbrella frame having a plurality of arms which, upon activation, bend outwardly to the enlarged condition.
5. The arterial cannula of claim 3, wherein the filter includes an expansion frame comprising an inflation seal.
6. The arterial cannula of claim 3, wherein the lumen of the 25 blood cannula terminates proximal to the filter.

7. The arterial cannula of claim 3, wherein the lumen of the blood cannula extends through the filter

8. The arterial cannula of claim 3, further comprising a handle slidably disposed about the blood cannula and enclosing the expandable filter and
5 balloon occluder when the expandable filter and balloon occluder are in the contracted condition, wherein the handle can be moved in a proximal direction to release the expandable filter and balloon occluder and allow same to be activated to the enlarged condition.

9. The arterial cannula of claim 5, further comprising a
10 pressurizing cannula shaped to receive the blood cannula and attached to the inflation seal.

10. The arterial cannula of claim 9, wherein the pressurizing cannula further includes an inflation system comprising a first lumen adapted to receive pressurized fluid and a second lumen adapted to evacuate gas, and
15 wherein the inflation seal further includes an entry port in fluid communication with the first lumen of the pressurizing cannula and an exit port in fluid communication with the second lumen of the pressurizing cannula, so that when fluid is advanced through the first lumen, the fluid enters the inflation seal and forces gas from the inflation seal through the second lumen, thereby purging the
20 system of gas.

11. The arterial cannula of claim 10, wherein the inflation seal comprises a tubular balloon which encloses a chamber, and wherein the entry port and exit port are in close proximity, and wherein a septum is disposed between the entry and exit ports.

25 12. The arterial cannula of claim 11, further comprising a plurality of holding strings which attach the inflation seal to the pressurizing cannula.

13. The arterial cannula of claim 12, wherein the holding strings are comprised of Dacron.

14. The arterial cannula of claim 1, wherein the blood cannula is a substantially cylindrical member which includes, at its proximal end, a fitting which is shaped for attachment to a bypass-oxygenator machine.

15. The arterial cannula of claim 9, wherein the first lumen of the pressurizing cannula includes, at its proximal end, a luer fitting adapted to receive a syringe, and wherein the second lumen of the pressurizing cannula includes, at its proximal end, a luer fitting adapted to receive a cap.

10 16. The arterial cannula of claim 8, wherein the blood cannula further includes a rib disposed circumferentially about the outer surface at the distal end of the blood cannula, and wherein a distal end of the handle engages the rib to form a break-up seal when the inflation seal is in the deflated condition and the handle encloses the inflation seal.

15 17. The arterial cannula of claim 3, wherein the balloon occluder is disposed circumferentially about the blood cannula.

18. The arterial cannula of claim 3, wherein the balloon occluder is disposed at a radial position along the side of the blood cannula.

20 19. A method for protecting a patient from embolization during cardiac surgery, comprising the steps of:
providing an arterial cannula with associated filter, comprising a blood cannula having an outer surface, a distal end adapted to enter an artery, a proximal end adapted to receive blood, and a lumen which extends longitudinally from the proximal to the distal end, an expandable filter disposed about the distal end of the blood cannula which is expandable between a contracted condition and

an enlarged condition, and an occluder which is expandable between a contracted condition and an inflated condition;

introducing a distal end of the arterial cannula into the patient's aorta while the expandable filter is in the contracted condition;

5 expanding the expandable filter until the filter achieves contact with the lumen of the aorta;

expanding the occluder to occlude the aorta in a region upstream of the filter, and thereafter contracting the occluder, wherein embolic material dislodged from the aorta is captured in the filter of the arterial cannula; and

10 contracting the filter to the contracted condition and removing the arterial cannula and captured embolic material from the aorta.

20. The method of claim 19, wherein the proximal end of the blood cannula is adapted to receive blood from a bypass-oxygenator machine.

21. The method of claim 20, wherein the step of expanding the 15 occluder is followed by the steps of:

supplying blood to the aorta from a bypass-oxygenator machine by way of the blood cannula; and

performing a surgical procedure on at least one of the heart, aorta upstream of the occluder, and vasculature associated with the heart and/or aorta.

20 22. The method of claim 20, wherein the arterial cannula further comprises a pressurizing cannula shaped to receive the blood cannula and wherein the filter includes an inflation seal.

25 23. The method of claim 22, wherein the pressurizing cannula further includes an inflation system comprising a first lumen adapted to receive pressurized fluid and a second lumen adapted to evacuate gas, and wherein the inflation seal further includes an entry port in fluid communication with the first lumen of the pressurizing cannula and an exit port in fluid communication with the second lumen of the pressurizing cannula, so that when fluid is advanced

through the first lumen, the fluid enters the inflation seal and forces gas from the inflation seal through the second lumen, thereby purging the system of gas.

24. The method of claim 20, wherein the arterial cannula further comprises a handle slidably disposed about the blood cannula and 5 enclosing the filter and balloon occluder when the filter and the balloon occluder are in the contracted condition, and wherein the method of protecting a patient further comprises the step of moving the handle in a proximal direction to release the filter and balloon occluder and allow same to be activated to an expanded condition.

10 25. The method of claim 20, wherein the balloon occluder is disposed circumferentially about the blood cannula.

26. The method of claim 20, wherein the balloon occluder is disposed at a radial position along the side of the blood cannula.

27. An arterial balloon catheter comprising:
15 a flexible elongate member having an outer surface, a distal region adapted to enter an artery, and a proximal region;
an expandable filter disposed about the distal region of the elongate member which is expandable between a contracted condition and an enlarged condition; and
20 an occluder disposed about the distal region of the elongate member and distal to the filter, the occluder is expandable between a contracted condition and an expanded condition, wherein the occluder, when in the contracted condition is closely associated with the distal end of the elongate member, while the occluder expands to substantially occlude an artery upstream 25 of the filter.

28. The arterial cannula of claim 27, wherein the occluder is a balloon occluder comprising a flexible material surrounding a chamber.

29. The arterial balloon catheter of claim 28, wherein the expandable filter includes an umbrella frame having a plurality of arms which, upon activation, bend outwardly to the enlarged condition.

30. The arterial balloon catheter of claim 28, wherein the 5 expandable filter includes an inflation seal.

31. The arterial balloon catheter of claim 28, wherein the flexible elongate member extends through the filter.

32. The arterial balloon catheter of claim 30, wherein the flexible elongate member further includes an inflation system comprising a first 10 lumen adapted to receive pressurized fluid and a second lumen adapted to evacuate gas, and wherein the inflation seal further includes an entry port in fluid communication with the first lumen of the flexible elongate member and an exit port in fluid communication with the second lumen of the flexible elongate member, so that when fluid is advanced through the first lumen, the fluid enters 15 the inflation seal and forces gas from the inflation seal through the second lumen, thereby purging the system of gas.

33. The arterial balloon catheter of claim 32, wherein the inflation seal comprises a tubular balloon which encloses a chamber, and wherein the entry port and exit port are in close proximity, and wherein septum is 20 disposed between the entry and exit ports.

34. The arterial balloon catheter of claim 30, further comprising a plurality of holding strings which attach the inflation seal to the flexible elongate member.

35. The arterial balloon catheter of claim 34, wherein the 25 holding strings are comprised of Dacron®.

36. The arterial balloon catheter of claim 32, wherein the first lumen of the flexible elongate member includes, at its proximal end, a luer fitting adapted to receive a syringe, and wherein the second lumen of the pressurizing cannula includes, at its proximal end, a luer fitting adapted to receive a cap.

5 37. The arterial balloon catheter of claim 28, wherein the balloon occluder is disposed circumferentially about the flexible elongate member..

10 38. The arterial balloon catheter of claim 28, wherein the balloon occluder is disposed at a radial position along the side of the flexible elongate member..

15 39. An arterial cannula with associated filter, comprising:
a blood cannula having an outer surface, a distal end adapted to enter an artery, a proximal end adapted to receive blood or other fluids, and a lumen which extends longitudinally from the proximal to the distal end;
an expandable filter disposed about the distal end of the blood cannula which is expandable between a contracted condition and an enlarged condition;
a flow diffuser attached at the distal end of the blood cannula; and
an occluder which is expandable between a contracted condition
20 and an expanded condition, wherein the occluder, when in the contracted condition, is closely associated with the distal end of the blood cannula at a region proximal the filter, while the occluder expands upon activation to substantially occlude an artery upstream of the filter.

25 40. The arterial cannula of claim 39, wherein the flow diffuser is located inside the cannula lumen.

41. The arterial cannula of claim 40, wherein the flow diffuser is a conical shape.

42. The arterial cannula of claim 40, wherein the flow diffuser is helical.

43. The arterial cannula of claim 39, wherein the flow diffuser is attached external to the cannula lumen by a structural support.

5 44. The arterial cannula of claim 40, wherein the flow diffuser is connected to the filter by a shaft,

45. The arterial cannula of claim 39, wherein the flow diffuser is a planar surface located at the distal end of the lumen.

46. An arterial cannula with associated filter, comprising:
10 a blood cannula having an outer surface, a distal end adapted to enter an artery, a proximal end adapted to receive blood or other fluids, and a lumen which extends longitudinally from the proximal to the distal end;
15 an expandable filter disposed about the distal end of the blood cannula which is expandable between a contracted condition and an enlarged condition;

a filter sleeve attached distal to the closed end of the filter mesh;
and

20 an occluder which is expandable between a contracted condition and an expanded condition, wherein the occluder, when in the contracted condition, is closely associated with the distal end of the blood cannula at a region proximal the filter, while the occluder expands upon activation to substantially occlude an artery upstream of the filter.

47. The arterial cannula of claim 46, wherein the filter sleeve is attached to at least one roll-up control line and one unroll control line.

25 48. The arterial cannula of claim 47, wherein said control lines enter a control lumen.

49. The arterial cannula of claim 46, wherein the unrolled filter sleeve captures the filter.

50. The arterial cannula of claim 46, wherein the filter sleeve is in a rolled-up position.

5 51. The arterial cannula of claim 46, wherein the filter sleeve has a circular cross-section.

52. The arterial cannula of claim 46, wherein the filter sleeve has a thickness between 6 and 14 thousandths of an inch.

10 53. The arterial cannula of claim 47, further comprising a pulley attached to said unroll and roll-up control lines.

54. The arterial cannula of claim 39, wherein the cannula contains a collapsible section which, when collapsed, accommodates the filter.

55. The arterial cannula of claim 39, wherein the cannula is made from an elastic material.

15 56. The arterial cannula of claim 55, further comprising a stylet inserted within the cannula lumen.

57. A method for protecting a patient from embolization during cardiac surgery, comprising the steps of:

20 providing an arterial cannula with associated filter, and filter sleeve comprising a blood cannula having an outer surface, a distal end adapted to enter an artery, a proximal end adapted to receive blood, and a lumen which extends longitudinally from the proximal to the distal end, an expandable filter having an openable end and a closed end, and disposed about the distal end of the blood cannula which is expandable between a contracted condition and an

enlarged condition, a filter sleeve attached distal to the closed end of the filter and an occluder which is expandable between a contracted condition and an inflated condition;

- introducing a distal end of the arterial cannula into the patient's aorta while the expandable filter is in the contracted condition;
- expanding the filter until the filter achieves contact with the lumen of the aorta;
- expanding the occluder to occlude the aorta in a region upstream of the filter, and thereafter contracting the occluder, wherein embolic material dislodged from the aorta is captured in the filter;
- unrolling the filter sleeve to capture and compress the filter; and removing the arterial cannula and captured embolic material from the aorta.

58. The method of claim 57, wherein the filter sleeve is controlled by a set of control lines.

59. The method of claim 20, wherein the step of expanding the filter is preceded by the step of rolling up the filter sleeve.

60. The method of claim 59, wherein the steps of rolling and unrolling the filter sleeve are accomplished by exerting force to control lines attached to the filter sleeve.

61. An arterial catheter comprising:

- a flexible elongate member having an outer surface, a distal region adapted to enter an artery, and a proximal region;
- an expandable filter disposed about the distal region of the elongate member which is expandable between a contracted condition and an enlarged condition;
- a filter sleeve attached proximal to the closed end of the filter; and

an occluder disposed about the distal region of the elongate member and distal to the filter, the occluder is expandable between a contracted condition and an expanded condition, wherein the occluder, when in the contracted condition is closely associated with the distal end of the elongate member at a region distal to the filter, while the occluder expands to substantially occlude an artery upstream of the filter.

5 62. The arterial catheter of claim 61, wherein the filter sleeve is attached to at least one roll-up control line and one unroll control line.

10 63. The arterial catheter of claim 62, wherein said control lines enter a control lumen.

64. The arterial catheter of claim 61, wherein the unrolled filter sleeve captures the filter.

65. The arterial balloon catheter of claim 61, wherein the filter sleeve is in a rolled-up position.

15 66. The arterial balloon catheter of claim 61, wherein the filter sleeve has a circular cross-section.

67. The arterial catheter of claim 61, wherein the filter sleeve has a thickness between 6 and 14 thousandths of an inch.

20 68. The arterial catheter of claim 62, further comprising a pulley attached to said unroll and roll-up control lines.

69. The arterial catheter of claim 61, wherein the occluder is a balloon occluder comprising a flexible material surrounding a chamber.

70. The arterial catheter of claim 27, wherein the proximal region of the flexible elongate member includes at least one opening of a blood lumen located on the arterial side of the occluder.

71. The arterial catheter of claim 27, wherein the distal region 5 of the flexible elongate member includes at least one lumen with an opening distal to the occluder.

72. The arterial catheter of claim 61, wherein the expandable filter includes an expansion frame and a mesh.

10 73. The arterial cannula of claim 1, further comprising a fluid-isolated conduit with at least one opening proximal to the occluder.

74. The arterial cannula of claim 1, wherein the occluder comprises a mechanical dam structure with lift arms, and wherein the dam includes a sealing balloon disposed circumferentially about its outer edge.

15 75. The arterial cannula of claim 1, wherein the occluder comprises a balloon filled with self-expanding foam.

76. The arterial cannula of claim 1, wherein the occluder comprises an expanding wire which radially expands when compressed longitudinally.

20 77. The arterial cannula of claim 1, wherein the occluder cannula includes seating bumps for additional sealing with the lumen of the aorta and infusion ports for cardioplegia solution, and wherein the cannula is L-shaped and flexible to allow for self-centering.

25 78. A method for protecting a patient from embolization during cardiac surgery, comprising the steps of:

providing an arterial cannula with associated filter comprising a blood cannula having an outer surface, a distal end adapted to enter an artery, a proximal end adapted to receive blood, a lumen which extends longitudinally from the proximal to the distal end, an expandable filter disposed about the distal 5 end of the blood cannula which is expandable between a contracted condition and an enlarged condition;

providing an occluder cannula having an outer surface, a distal end adapted to enter an aorta, a proximal end adapted to receive cardioplegia fluid, a lumen which extends longitudinally from the proximal to the distal end, an 10 expandable occluder disposed about the distal end of the occluder cannula which is expandable between a contracted condition and an enlarged condition, wherein the occluder expands upon activation to substantially occlude the aorta upstream of the filter;

introducing the distal end of the arterial cannula into the patient's 15 aorta while the expandable filter is in the contracted condition;

expanding the expandable filter until the filter achieves contact with the lumen of the aorta;

introducing the distal end of the occluder cannula into the patient's aorta upstream of the arterial cannula while the expandable occluder is in the 20 contracted condition;

expanding the expandable occluder to occlude the aorta;
contracting the occluder;

removing the occluder cannula from the aorta; and
contracting the filter to the contracted condition and removing the 25 arterial cannula,

wherein embolic material dislodged from the aorta is captured by the filter of the arterial cannula and removed from the aorta.